

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of Earliest Event Reported): November 5, 2020**

**Amarin Corporation plc**  
(Exact name of registrant as specified in its charter)

**England and Wales**  
(State or other jurisdiction  
of incorporation)

**0-21392**  
(Commission  
File Number)

**Not applicable**  
(I.R.S. Employer  
Identification No.)

**77 Sir John Rogerson's Quay, Block C,  
Grand Canal Docklands, Dublin 2, Ireland**  
(Address of principal executive offices)

**Not applicable**  
(Zip Code)

**Registrant's telephone number, including area code: +353 1 6699 020**

**Not Applicable**  
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02. Results of Operations and Financial Condition.**

On November 5, 2020, Amarin Corporation plc issued a press release announcing its financial results for the three and nine months ended September 30, 2020 (the “Press Release”). A copy of the Press Release is furnished herewith as Exhibit 99.1.

*The information in this report furnished pursuant to Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.*

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	<a href="#">Press Release, dated November 5, 2020</a>
104	<a href="#">Cover Page Interactive Data File (embedded within the Inline XBRL document)</a>

\* \* \*

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 5, 2020

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer



## Amarin Reports Third Quarter 2020 Financial Results and Provides Business Update

*Total Revenue Increased 39% in Third Quarter 2020 and 56% in First Nine Months of 2020 Compared to Same Periods of 2019 Despite COVID-19 Headwinds*

*Progress Continues Towards VASCEPA® (icosapent ethyl) Approval and Commercialization in Europe*

*Management to Host Conference Call Today at 7:30 a.m. ET*

DUBLIN, Ireland and BRIDGEWATER, N.J., November 5, 2020 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the three and nine months ended September 30, 2020 and provided an update on company operations.

### **Key Achievements in Third Quarter 2020 (and recent weeks)**

- Achieved record quarterly and nine-month revenue levels: Reported \$156.5 million in net total revenue in the third quarter of 2020, an increase of 39% compared to the third quarter of 2019, resulting in net total revenue for the first nine months of \$446.8 million, an increase of 56% compared to the same period in 2019.
  - Reaffirmed strategy to continue increasing U.S. promotion of VASCEPA: As reported, the U.S. Court of Appeals for the Federal Circuit upheld the March 2020 U.S. District Court ruling in favor of two generic companies in connection with their abbreviated new drug applications, or ANDAs, related to VASCEPA capsules in its initial triglyceride lowering indication. While generic competition could potentially launch in the United States at any time, Amarin continues to expect that with enhanced education and promotional initiatives there is an opportunity to meaningfully grow revenue for VASCEPA in the United States. These incremental initiatives include direct-to-consumer advertisement, which launched for the new cardiovascular risk reduction indication in the third quarter of 2020. Such promotion builds on the important outreach to healthcare professionals made by our direct sales team, the size of which doubled near the start of 2020. Amarin's strategy and initiatives to further expand the market despite likely generic competition reflect the large number of at-risk patients who could potentially benefit from VASCEPA and survey data indicating that most healthcare professionals and at-risk patients are not yet aware of the benefits of VASCEPA in the cardiovascular risk reduction indication, which launched in early 2020. Amarin's decision to continue to invest in expanding the market for VASCEPA also reflects its confidence in its manufacturing processes, which the company has built over a decade to achieve consistent, high-quality, stable supply to support anticipated global demand.
  - Progressed European regulatory review and commercial preparations: Continued to support regulatory review of VASCEPA by the European Medicines Agency (EMA) with the expectation of an early 2021 approval of VASCEPA for commercial sale in Europe. In the process of hiring select people with extensive commercial experience in Europe and preparing for post-approval market access negotiations.
  - Expanded medical society recommendations in support of the efficacy and safety of VASCEPA: The European Society of Cardiology expanded their guidelines to recommend use of VASCEPA in treating acute coronary syndrome patients. Previously they had recommended use of VASCEPA for treating patients with established cardiovascular disease.
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- Reported additional VASCEPA clinical results and other data that further define VASCEPA's multifactorial mechanisms of action, clinical need and effects in reducing cardiovascular risk: EVAPORATE study results reported in August 2020 showed a 17% reduction in coronary plaque over 18 months in patients with established coronary plaque. REDUCE-IT® PCI results presented in October 2020 showed through *post hoc* subgroup analyses that patients in the REDUCE-IT study who had stenting, bypass or other forms of percutaneous cardiovascular intervention (PCI) experienced significantly reduced rates of ischemic events when treated with VASCEPA. REDUCE-IT RENAL results presented in October 2020 showed, through prespecified and *post hoc* subgroup analyses, that patients in the REDUCE-IT study who had compromised renal function at baseline prior to treatment with VASCEPA or placebo, experienced higher rates of cardiovascular events than the overall population studied in REDUCE-IT. Additionally, VASCEPA use in the treatment of such patients with baseline decreased renal function resulted in similarly favorable relative risk reductions and numerically greater absolute risk reductions versus placebo in comparison with the overall patient population.
- Reaffirmed clinical trial results from study of VASCEPA in China are expected by year end 2020: Assuming positive results from this study conducted by Amarin's commercial partner for VASCEPA in China, regulatory submission in China could follow promptly thereafter.
- Advanced enrollment in three COVID-19 related pilot studies: Clinical studies of VASCEPA in Argentina, Canada and the United States each reported substantial patient enrollment. These are investigator-initiated studies which Amarin supports but does not manage, and the clinical data being collected from these studies are blinded. Final results from these studies are expected to be available some time in 2021. Mechanistic data continues to provide reasons to believe that VASCEPA could potentially be beneficial to lessen the impact of COVID-19.
- Maintained strong cash balance and reduced debt: As of September 30, 2020, Amarin reported total cash and investments of \$608.0 million and \$9.5 million remaining debt on its royalty-like instrument, which Amarin plans to pay in full during the fourth quarter of 2020.

### ***Management Commentary***

"The third quarter was a productive but challenging quarter for Amarin as total net revenue grew to record levels reflecting increased prescription levels for VASCEPA, despite many patients not yet returning to their doctors' offices for preventative healthcare due to the global pandemic," stated John F. Thero, president and chief executive officer. "We believe the key court decisions regarding VASCEPA patents related to the triglyceride lowering indication have been wrong and we plan to continue to pursue this matter to the highest level. Moreover, we believe that because of numerous factors, including that VASCEPA was only recently launched as the first and only drug for its cardiovascular risk reduction indication, that continued investment is justified in market expansion with the expectation that increased revenue and profit can accumulate for Amarin by doing so. We remain focused on bringing this potentially life-saving drug to at-risk patients in the United States, Europe and elsewhere in the world."

"We are excited to be nearing the EMA's regulatory decision on VASCEPA and are busy preparing for our anticipated commercial launch in Europe, where there is a large and growing opportunity for Amarin to bring this proven effective therapy to the millions of patients at high risk for cardiovascular events. Launching on our own in major markets in Europe allows us to create the greatest value as Amarin would not have to share profits with a partner. Importantly, we can leverage the knowledge and experience gained from the tremendous progress made by our U.S. commercial team.

"In the coming months, we expect to achieve a number of key milestones including the topline data readout from the Phase 3 clinical trial of VASCEPA in China with our partner, Eddingpharm; a recommendation from the Committee for Medicinal Products for Human Use (CHMP) relating to our European regulatory review and approval process; and

presentation of numerous data in support of VASCEPA in the cardiovascular risk reduction indication at the upcoming Annual Scientific Sessions of the American Heart Association,” added Mr. Thero.

#### ***Prescription Growth***

Normalized prescriptions for VASCEPA (prescription of 120 grams of VASCEPA representing a one-month supply) increased by approximately 36% and 37% in the third quarter of 2020 compared to the same period in 2019 based on data from Symphony Health and IQVIA, respectively. Estimated normalized VASCEPA prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 1,174,000 and 1,081,000 in the third quarter of 2020. Year to date, estimated normalized prescriptions for VASCEPA increased by approximately 49% and 51%, compared to the first nine months of 2019 based on data from Symphony Health and IQVIA, respectively. Estimated normalized VASCEPA prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 3,325,000 and 3,050,000 in the first nine months of 2020, respectively.

As with much of the pharmaceutical industry, VASCEPA revenue and prescription growth have been adversely impacted by the COVID-19 pandemic. Amarin temporarily suspended in-person promotional activities in March 2020 and beginning in June 2020 in a phased approach, resumed face-to-face interactions with healthcare providers, to the extent such healthcare providers allow, and recently substantially all sales force personnel are permitted to resume face-to-face interaction. This has been done in a manner consistent with guidelines from local, state and government health officials in the United States, although such permission may be further restricted if geographies continue to experience a resurgence of the pandemic. Due to various state and local shelter in place and other travel restrictions, reports from IQVIA indicated that patient visits to medical offices in April were down approximately 70% compared to pre-COVID-19 levels. Similarly, IQVIA reported a significant drop in the number of routine lab tests, including blood tests, being conducted. Physicians typically require office visits, including physical examinations and blood tests, prior to prescribing new medications such as VASCEPA.

Commencing in September 2020, weekly normalized prescriptions reached levels consistent with, or slightly higher than, pre-COVID-19 levels. According to IQVIA data, in September 2020 the number of patient visits to health care providers increased meaningfully over the lows of April 2020 but remained below the volume levels reported prior to mid-March 2020 when the impact of COVID-19 began to significantly affect the United States. Amarin is optimistic that the worst period of impact from COVID-19 on the levels of patients seeking ordinary course doctor visits and lab tests may be behind it. Amarin expects, however, that the COVID-19 dynamic will continue to have an unfavorable impact on revenue, at least in the near term. Accordingly, the degree and timing for potential reacceleration of VASCEPA revenue growth is uncertain, particularly if there are resurgences in the spread of the infection in various geographies and a reinforcement of social distancing and other protocols.

While Amarin’s field team continues to utilize, as necessary, various means to interact with healthcare professionals virtually, such interactions tend to be less frequent and potentially less impactful than in-person communications. This is particularly the case because VASCEPA is being newly introduced to many healthcare professionals as a treatment for cardiovascular risk reduction based on its second FDA indication, launched in January 2020.

#### ***Increasing Promotion in the United States***

To augment Amarin’s ongoing activities to educate healthcare professionals and in parallel with the sales team getting back into the field, Amarin launched its first ever direct-to-consumer campaign focused on the use of VASCEPA for cardiovascular risk reduction in indicated patients in mid-July 2020. The campaign highlights persistent cardiovascular risk and the benefit of VASCEPA to reduce risk of a heart attack or stroke by 25% when added to a statin. The campaign is intended to raise awareness of VASCEPA among both healthcare professionals and consumers and encourages patients to ask their providers about VASCEPA. As healthcare professionals and patients learn more about VASCEPA, Amarin anticipates expanded VASCEPA prescriptions and revenue. However, the timing and magnitude of such increases remain

difficult to predict due to the challenges of quantifying the pace and stability of COVID-19 recovery and the unprecedented nature and limited history of VASCEPA's approved indication.

#### **Financial Update**

Net total revenue for the three and nine months ended September 30, 2020 were \$156.5 million and \$446.8 million, respectively, compared to \$112.4 million and \$286.5 million in the corresponding periods of 2019, respectively, indicating increases of 39% and 56%, respectively. Net product revenue for the three and nine months ended September 30, 2020 were \$155.2 million and \$441.1 million, respectively, compared to \$112.3 million and \$285.3 million in the corresponding periods of 2019, respectively, indicating increases of 38% and 55%, respectively. The increase in net product revenue was driven primarily by increased volume of VASCEPA sales to customers in the United States, as well as a modest increase in VASCEPA's net selling price in the United States, reflecting various factors including managed care coverage improvements. The increase was also driven by VASCEPA sales outside of the United States of approximately \$0.5 million and \$8.9 million during the three and nine months ended September 30, 2020 as compared to nil and \$0.3 million during the three and nine months ended September 30, 2019, primarily as a result of an initial order in the first half of 2020 to ensure adequate product supply for Amarin's commercial partner's launch of VASCEPA in Canada (recognized upon shipment by Amarin to that partner).

In addition, Amarin recognized licensing and royalty revenue of approximately \$1.3 million and \$5.7 million in the three and nine months ended September 30, 2020, respectively, under agreements for the commercialization of VASCEPA outside the United States. This compares with licensing and royalty revenue of \$0.2 million and \$1.1 million in the same periods of 2019, respectively.

Cost of goods sold for the three and nine months ended September 30, 2020 was \$33.1 million and \$96.7 million, respectively, compared to \$25.4 million and \$65.4 million in the corresponding periods of 2019, respectively. Amarin's overall gross margin on net product revenue for the three and nine months ended September 30, 2020 was 79% and 78%, respectively, compared to 77% for the three and nine months ended in 2019. This increase in gross margin on net product sales is driven by gross margin on U.S. product sales of 79% for the three and nine months ended September 30, 2020, partially offset by the gross margin on product sales to Amarin's partners outside the United States to which, under contractual agreements, we generally sell product on a cost-plus basis with licensing and royalty revenue separately recorded.

Selling, general and administrative (SG&A) expense for the three and nine months ended September 30, 2020 were \$120.2 million and \$346.5 million, respectively, compared to \$82.6 million and \$227.6 million, respectively, in the corresponding periods of 2019, representing increases of 46% and 52%. This increase is primarily due to personnel costs related to the sales force expansion as well as an increase in promotional activity following the launch of VASCEPA, including consumer-focused promotion which was augmented in July 2020 when Amarin launched its first television advertisement of VASCEPA focused on cardiovascular risk reduction based on the product's new label.

Research and development (R&D) expense for the three and nine months ended September 30, 2020 were \$10.2 million and \$30.5 million, respectively, compared to \$8.9 million and \$23.3 million, respectively, in the corresponding periods of 2019, representing increases of 14% and 31%, respectively. The increase in expense was primarily driven by costs beyond the conduct of the REDUCE-IT study to further analyze samples collected from REDUCE-IT patients as well as costs associated with the achievement of certain milestones under Amarin's strategic collaboration agreement with Mochida and costs to support various publications and pilot studies.

Under U.S. GAAP, Amarin reported a net loss of \$6.8 million in the three months ended September 30, 2020, or basic and diluted loss per share of \$0.02, which included \$11.6 million in non-cash stock-based compensation expense. In comparison, Amarin reported a net loss of \$3.5 million for the third quarter of 2019, or basic and diluted loss per share of \$0.01, which included \$8.0 million in non-cash stock-based compensation expense.

Under U.S. GAAP, Amarin reported a net loss of \$22.9 million for the nine months ended September 30, 2020, or basic and diluted loss per share of \$0.06, which included \$34.3 million in non-cash stock-based compensation expense. In comparison, Amarin reported a net loss of \$29.7 million, or basic and diluted loss per share of \$0.09 for the nine months ended September 30, 2019, which included \$22.7 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$4.8 million for the third quarter of 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.01, compared to non-GAAP adjusted net income of \$4.5 million for the third quarter of 2019, or non-GAAP adjusted basic and diluted earnings per share of \$0.01.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$11.4 million for the nine months ended September 30, 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.03, compared to non-GAAP adjusted net loss of \$7.0 million for the nine months ended September 30, 2019, or non-GAAP adjusted basic and diluted loss per share of \$0.02.

As of September 30, 2020, Amarin reported aggregate cash and investments of \$608.0 million, consisting of cash and cash equivalents of \$207.2 million and liquid short-term and long-term investments of \$354.7 and \$46.1 million, respectively. As of September 30, 2020, Amarin reported \$147.3 million in net accounts receivable (\$223.6 million in gross accounts receivable before allowances and reserves) and \$148.5 million in inventory. Further, Amarin plans to pay the remaining \$9.5 million of its debt during the fourth quarter of 2020. Once repaid, Amarin will have no debt obligations.

As previously expressed, until uncertainties regarding the effects and duration of the COVID-19 pandemic and the scope of potential generic competition are better understood, Amarin is not providing an estimate of expected 2020 revenue results. Based on its current plans and expectations, Amarin believes that its current capital resources are sufficient to achieve sustained positive cash flows from VASCEPA, including commercial launch of VASCEPA in Europe. Results are anticipated to vary significantly on a quarterly basis including some likely negative net cash flow periods. Factors that are expected to contribute to this variability include the cost and response to, Amarin's educational and promotional initiatives to advance its launch in the United States of VASCEPA in its new cardiovascular risk reduction indication; the continued and varied impact of the COVID-19 pandemic on Amarin's business and society; the potential launch of generic versions of VASCEPA in the United States; and the cost and response to Amarin's efforts toward the further development and launch of VASCEPA in Europe. While Amarin believes that it has adequate supply to support likely near-term sales demand, the company intends to continue to purchase supply as needed to support anticipated VASCEPA growth in the United States and globally.

As of September 30, 2020, Amarin had approximately 388.8 million American Depositary Shares (ADSs) and ordinary shares outstanding, 2.4 million common share equivalents of Series A Convertible Preferred Shares outstanding, approximately 17.5 million equivalent shares underlying stock options at a weighted-average exercise price of \$7.84, and 7.7 million equivalent shares underlying restricted or deferred stock units.

### ***Conference Call and Webcast Information***

Amarin will host a conference call November 5, 2020, at 7:30 a.m. ET to discuss this information. The conference call can be heard live on the investor relations section of the company's website at [www.amarincorp.com](http://www.amarincorp.com) or via telephone by dialing 877-407-8033 within the United States, 201-689-8033 from outside the United States. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010, PIN: 38230. A replay of the call will also be available through the company's website shortly after the call.

### ***Use of Non-GAAP Adjusted Financial Information***



Included in this press release are non-GAAP adjusted financial information as defined by U.S. Securities and Exchange Commission Regulation G. The GAAP financial measure most directly comparable to each non-GAAP adjusted financial measure used or discussed, and a reconciliation of the differences between each non-GAAP adjusted financial measure and the comparable GAAP financial measure, is included in this press release after the condensed consolidated financial statements.

Non-GAAP adjusted net income (loss) was derived by taking GAAP net income (loss) and adjusting it for non-cash stock-based compensation expense. Management uses these non-GAAP adjusted financial measures for internal reporting and forecasting purposes, when publicly providing its business outlook, to evaluate the company's performance and to evaluate and compensate the company's executives. The company has provided these non-GAAP financial measures in addition to GAAP financial results because it believes that these non-GAAP adjusted financial measures provide investors with a better understanding of the company's historical results from its core business operations.

While management believes that these non-GAAP adjusted financial measures provide useful supplemental information to investors regarding the underlying performance of the company's business operations, investors are reminded to consider these non-GAAP measures in addition to, and not as a substitute for, financial performance measures prepared in accordance with GAAP. Non-GAAP measures have limitations in that they do not reflect all of the amounts associated with the company's results of operations as determined in accordance with GAAP. In addition, it should be noted that these non-GAAP financial measures may be different from non-GAAP measures used by other companies, and management may utilize other measures to illustrate performance in the future.

#### **About Amarin**

Amarin Corporation plc is a rapidly growing, innovative pharmaceutical company focused on developing and commercializing therapeutics to cost-effectively improve cardiovascular health. Amarin's lead product, VASCEPA® (icosapent ethyl), is available by prescription in the United States, Canada, Lebanon and the United Arab Emirates. VASCEPA is not yet approved and available in any other countries. Amarin, on its own or together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in China, Europe and the Middle East. For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).

#### **About Cardiovascular Risk**

The number of deaths in the United States attributed to cardiovascular disease continues to rise. There are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds), in the United States. Stroke rates are 795,000 per year (approximately 1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. Cardiovascular disease results in 859,000 deaths per year in the United States.<sup>1</sup> In aggregate, there are more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, one every 13 seconds in the United States alone.

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk for cardiovascular events, such as heart attack, stroke or death. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent risk of cardiovascular events, especially those patients with elevated triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35%.<sup>2</sup> Significant cardiovascular risk remains after statin therapy. People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.<sup>3,4,5</sup>

#### **About REDUCE-IT®**

REDUCE-IT was a global cardiovascular outcomes study designed to evaluate the effect of VASCEPA in adult patients with LDL-C controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides between 135-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other cardiovascular risk factor (primary prevention cohort).

REDUCE-IT, conducted over seven years and completed in 2018, followed 8,179 patients at over 400 clinical sites in 11 countries with the largest number of sites located within the United States. REDUCE-IT was conducted based on a special protocol assessment agreement with FDA. The design of the REDUCE-IT study was published in March 2017 in *Clinical Cardiology*.<sup>6</sup> The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.<sup>7</sup> The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.<sup>8</sup> These and other publications can be found in the R&D section on the company's website at [www.amarincorp.com](http://www.amarincorp.com).

### **About VASCEPA® (icosapent ethyl) Capsules**

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the FDA comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over eight million times. VASCEPA is covered by most major medical insurance plans. The new, cardiovascular risk indication for VASCEPA was approved by the FDA in December 2019.

### Indications and Limitation of Use

VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  mg/dL) and
  - established cardiovascular disease or
  - diabetes mellitus and two or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

### Important Safety Information

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence  $\geq 3\%$  and  $\geq 1\%$  more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).
- Common adverse reactions in the hypertriglyceridemia trials (incidence  $\geq 1\%$  more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA as set forth below:

**Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT**

	VASCEPA		Placebo		VASCEPA vs Placebo
	N = 4089 n (%)	Incidence Rate (per 100 patient years)	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)
<b>Primary composite endpoint</b>					
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705 (17.2)	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
<b>Key secondary composite endpoint</b>					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
<b>Other secondary endpoints</b>					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	2.1	0.69 (0.58, 0.81)
Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	1.9	0.65 (0.55, 0.78)
Cardiovascular death [1]	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	0.9	0.68 (0.53, 0.87)
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	0.8	0.72 (0.55, 0.93)
[1] Includes adjudicated cardiovascular deaths and deaths of undetermined causality. [2] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.					

**FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.**

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including expectations regarding financial metrics and performance such as prescription growth, revenue growth, operating expenses, inventory purchases, and managed care coverage for VASCEPA, including the impact of the COVID-19 pandemic, the outcome of patent litigation and the launch of generic competition on these metrics; the timing and outcome of regulatory reviews, recommendations and approvals and related reimbursement decisions in China, Europe and elsewhere; the timing and outcome of the clinical trial in China; the timing and outcome of Amarin's decision to launch VASCEPA directly in major markets in Europe and with a partner

potentially in some markets in Europe; the timing and outcome of Amarin's patent litigation efforts; the timing and outcome of promotion activities, including patient-oriented campaigns and education of healthcare professionals; commercial and international expansion, prescription growth and revenue growth and future revenue levels, including the contributions of recently hired sales representatives; the sufficiency of current capital resources to achieve sustained positive cash flows; ability of commercial supply to generic companies and Amarin; creditworthiness of its largest customers; expectations related to exclusivity in various jurisdictions and ongoing patent litigation appeal efforts and associated business plans in various scenarios; and the impact of the COVID-19 pandemic on all of the forgoing. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Amarin's ability to effectively commercialize VASCEPA will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for VASCEPA through education, marketing and sales activities, to achieve broad market acceptance of VASCEPA, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of VASCEPA and to secure and maintain patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may be determined to not be infringed or not be valid in patent litigation and applications may not result in issued patents sufficient to protect the VASCEPA franchise. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

### **Availability of Other Information About Amarin**

Investors and others should note that Amarin communicates with its investors and the public using the company website ([www.amarincorp.com](http://www.amarincorp.com)), the investor relations website ([investor.amarincorp.com](http://investor.amarincorp.com)), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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**CONSOLIDATED BALANCE SHEET DATA**  
**(U.S. GAAP)**  
**Unaudited**

	September 30, 2020	December 31, 2019
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 207,207	\$ 644,588
Restricted cash	3,915	3,907
Short-term investments	354,655	—
Accounts receivable, net	147,292	116,430
Inventory	148,531	76,769
Prepaid and other current assets	26,945	13,311
Total current assets	888,545	855,005
Property, plant and equipment, net	2,166	2,361
Long-term investments	46,092	—
Operating lease right-of-use asset	8,149	8,511
Other long-term assets	1,074	1,074
Intangible asset, net	14,177	15,258
TOTAL ASSETS	\$ 960,203	\$ 882,209
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 121,366	\$ 49,950
Accrued expenses and other current liabilities	189,650	139,826
Debt from royalty-bearing instrument	9,467	50,130
Deferred revenue, current	5,706	2,342
Total current liabilities	326,189	242,248
Long-Term Liabilities:		
Deferred revenue, long-term	13,199	18,504
Long-term operating lease liability	9,255	9,443
Other long-term liabilities	4,303	3,751
Total liabilities	352,946	273,946
Stockholders' Equity:		
Preferred stock	5,434	21,850
Common stock	287,585	269,173
Additional paid-in capital	1,799,069	1,764,317
Treasury stock	(50,728)	(35,900)
Accumulated deficit	(1,434,103)	(1,411,177)
Total stockholders' equity	607,257	608,263
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 960,203	\$ 882,209

**CONSOLIDATED STATEMENTS OF OPERATIONS DATA**  
**(U.S. GAAP)**  
**Unaudited**

	<b>Three months ended September 30,</b> <b>(in thousands, except per share amounts)</b>		<b>Nine months ended September 30,</b> <b>(in thousands, except per share amounts)</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Product revenue, net	\$ 155,190	\$ 112,250	\$ 441,118	\$ 285,347
Licensing and royalty revenue	1,309	158	5,691	1,131
Total revenue, net	156,499	112,408	446,809	286,478
Less: Cost of goods sold	33,071	25,444	96,676	65,354
Gross margin	123,428	86,964	350,133	221,124
Operating expenses:				
Selling, general and administrative (1)	120,164	82,559	346,496	227,598
Research and development (1)	10,204	8,923	30,450	23,295
Total operating expenses	130,368	91,482	376,946	250,893
Operating loss	(6,940)	(4,518)	(26,813)	(29,769)
Interest income, net	549	1,146	1,908	238
Other income (expense), net	33	(90)	50	(182)
Loss from operations before taxes	(6,358)	(3,462)	(24,855)	(29,713)
Income tax (provision) benefit	(430)	—	1,929	—
Net loss	\$ (6,788)	\$ (3,462)	\$ (22,926)	\$ (29,713)
Loss per share:				
Basic	\$ (0.02)	\$ (0.01)	\$ (0.06)	\$ (0.09)
Diluted	\$ (0.02)	\$ (0.01)	\$ (0.06)	\$ (0.09)
Weighted average shares:				
Basic	389,699	350,994	378,770	336,938
Diluted	389,699	350,994	378,770	336,938

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$110,241 and \$75,803 for the three months ended September 30, 2020 and 2019, respectively, and research and development expenses were \$8,544 and \$7,716, respectively, for the same periods.

# RECONCILIATION OF NON-GAAP NET INCOME (LOSS)

## Unaudited

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2020	2019	2020	2019
Net loss for EPS <sup>1</sup> - GAAP	\$ (6,788)	\$ (3,462)	\$ (22,926)	\$ (29,713)
Non-cash stock-based compensation expense	11,583	7,963	34,306	22,729
Adjusted net income (loss) for EPS <sup>1</sup> - non-GAAP	\$ 4,795	\$ 4,501	\$ 11,380	\$ (6,984)
Basic and diluted				
Earnings (loss) per share:				
Basic - non-GAAP	\$ 0.01	\$ 0.01	\$ 0.03	\$ (0.02)
Diluted - non-GAAP	0.01	0.01	0.03	(0.02)
Weighted average shares:				
Basic	389,699	350,994	378,770	336,938
Diluted	399,400	373,238	401,454	336,938

## References

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